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EXAMINER
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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/700,649	Applicant(s) FREEMAN ET AL.	
	Examiner ALEX NOGUEROLA	Art Unit 1743	

-- The MAILING DATE of this communication appears on th cov r sheet with th correspond nc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 May 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,15-18,20,21 and 23* is/are rejected.

7)☒ Claim(s) *13,14,19 and 22* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 May 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-3, 5, and 16-18 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Shine et al. (WO 9724600 A1).

Addressing Claim 1, Shine et al. teach a microelectrode system comprising a laminated structure (the abstract; Figures 3 and 6; and page 7, ll. 1-4) having at least one conducting layer capable of acting as an electrode (**3** or **14** in Figure 3 or **203** or **214** in Figure 6), at least one dielectric layer (**2** in Figure 3 or the unlabeled insulating layer between electrodes **203** and **214** in Figure 6), and contact means for allowing electrical contact with at least one conducing layer (**10** or **17** in Figure 3 or **210** or **217** in Figure 6).

Addressing Claim 2, an aperture defining a non-uniform internal wall may be seen in Figures 3 and 6.

Addressing Claim 3, an aperture defining a substantially tubular internal wall in the laminate structure is shown in Figures 3, 4, and 6.

Addressing Claim 5, that the aperture is a through-hole as claimed may be seen in Figures 3 and 6.

Addressing Claim 16, a gold conducting layer is disclosed on page 10, lines 16-19.

Addressing Claim 17, a dielectric layer as claimed is disclosed on page 10, lines 8-15 and Figures 3 and 6.

Addressing Claim 18, syringes are disclosed in Figure 7.

3. Claims 1-3, 5, 18, and 21 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Friese et al. (US 5,314,604).

Addressing Claim 1, Friese et al. teach a microelectrode system comprising a laminated structure (the abstract; Figures 1A and 2A; and col. 4, ll. 52-54) having at least one conducting layer capable of acting as an electrode (**6**, **8**, or **8'** in Figures 1A or 2A), at least one dielectric layer (col. 4, ll. 10-14), and contact means for allowing electrical contact with at least one conducing layer (**6'**, **9'**, or **11'** in Figures 1A, 1B, 2A, or 2B).

Addressing Claim 2, an aperture defining a non-uniform internal wall may be seen in Figures 1A and 2A.

Addressing Claim 3, an aperture defining a substantially tubular internal wall in the laminate structure is shown in Figures 1 and 2.

Addressing Claim 5, that the aperture is a through-hole as claimed may be seen in Figures 1A and 2A.

Addressing Claim 18, electrode pumps are disclosed in col. 3, ll. 22-25.

Addressing Claim 21, solid electrolyte layers are disclosed in col. 3, ll. 14-20.

4. Claims 1, 2, 4, 5, 7, 15, 16, 21, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Knoll (US 5,393,401).

Addressing Claim 1, Knoll teach an electrode system comprising a laminated structure (the abstract; Figures 4 and 7-10) having at least one conducting layer capable of acting as an electrode (**16**, **32**, or **33** in Figures 4 and 7-10), at least one dielectric layer (**15** in Figures 4 and 7-10), and contact means for allowing electrical contact with at least one conducing layer (not shown in the figures but implied by, for example, col. 7, ll. 10-13, which teaches an electrical connection to an integrated circuit). Knoll does not mention that the electrode system is a microelectrode system; however, this is implied by col. 5, ll. 51-54, which teaches that the wafer (which is thicker than the conducting layer) is less than 1 mm thick.

Addressing Claim 2, an aperture defining a non-uniform internal wall may be seen in Figures 4 and 7-10.

Addressing Claim 4, a plurality of apertures is implied by Figure 4, which shows a schematic for an array of sensors.

Addressing Claim 5, that the aperture is intended to be a through-hole as claimed may be seen from Figure 12.

Addressing Claim 7, electrode **16** or **32** is fictionalized by the ionophore in membrane **7**.

Addressing Claim 15, a silver/silver chloride reference electrode is taught in col. 8, ll. 13-19 and col. 8, ll. 37-44.

Addressing Claim 16, a gold conducting layer is disclosed in col. 7, ll. 1-10.

Addressing Claims 21 and 23, in the aperture, level with a dielectric layer, gel, solid electrolyte, and membrane containing ionophore may be present (col. 8, ll. 20-30.

5. Claims 1-4, 6, 9, 11, 16, and 20 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Maracas et al. (US 5,727,977).

Addressing Claim 1, Maracas et al. teach a microelectrode system comprising a laminated structure (the abstract; Figures 1, 15, 18-20, 24, or 30; col. 6, ll. 52-54; and col. 2, ll. 59-61) having at least one conducting layer capable of acting as an electrode (**103, 105, 106, 203, 206, 216, 303, 306, 406, 403** or **14** in Figures 1, 15, 18-20, 24, or 30), and at least one dielectric layer (**102, 202, 205, 209, 210, 302, 305, 309, 402, 405, 409, 410** in Figures 1, 15, 18-20, 24, or 30). Contact means for allowing electrical contact with at least one conducing layer are not shown in the figures, but are implied by the disclosure since the device is an electron-emitter that emits electrons from the conducting layer.

Addressing Claim 2, an aperture defining a uniform or a non-uniform internal wall may be seen in Figures 1, 15, 18-20, 24, and 30.

Addressing Claim 3, an aperture defining a substantially tubular internal wall in the laminate structure is shown in Figure 20.

Addressing Claim 4, a plurality of apertures is shown in Figure 20.

Addressing Claim 6, an aperture in the form of a well as claimed may be seen in Figures 1, 15, 18, 19, 20, 24, and 30.

Addressing Claim 9, as seen in Figures 18, 19, 20, 24, and 30 consecutive conducting layers are separated by dielectric layers.

Addressing Claim 11, substantially collinear wells as claimed may be seen in Figure 20.

Addressing Claim 16, a gold conducting layer is disclosed in col. 4, ll. 33-36.

Addressing Claim 20, alternating conducting and dielectric layers are disclosed in Figures 1, 18-20, 24, and 30.

6. Claims 1-3, 5, 7, 9, 15-17, and 20 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Watanabe et al. (US 4,647,362).

Addressing Claim 1, Watanabe et al. teach a microelectrode system comprising a laminated structure (the abstract; Figure 1; and col. 3, ll. 60-65) having at least one conducting layer capable of acting as an electrode (any metal layer **2** shown Figure 1), at least one dielectric layer (any insulating layer **1** shown in Figure 1), and contact means for allowing electrical contact with at least one conducing layer (any lead **8** shown in Figure 1).

Addressing Claim 2, an aperture defining a uniform internal wall in the laminate structure is shown in Figure 1.

Addressing Claim 3, an aperture defining a substantially tubular internal wall in the laminate structure is shown in Figure 1.

Addressing Claim 5, that the aperture is a through-hole as claimed may be seen in Figure 1.

Addressing Claim 7, electrode **2** (shown in magnified view as **24** in Figure 1) is fictionalized by ion sensitive layer **3.**

Addressing Claim 9, as seen in Figure 1 consecutive conducting layers are separated by dielectric layers.

Addressing Claim 15, a silver/silver chloride reference electrode is taught in col. 4, ll. 2-14.

Addressing Claim 16, a gold conducting layer is disclosed in col. 3, ll. 65-67.

Addressing Claim 17, a dielectric layer as claimed is disclosed in col. 3, ll. 50-59 and Figure 1.

Addressing Claim 20, alternating conducting and dielectric layers are disclosed in Figure 1.

7. Claims 1, 2, 4, 6, 8, 10, 11, and 16 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by JPO computer translation of Fukuda (JP 06324014 A).

Addressing Claim 1, Fukuda teaches a microelectrode system comprising a laminated structure (the abstract; Drawings 2 and 4-6; paragraph [0022] of the *Detailed Description*; and paragraph [0029] of the *Detailed Description*), having at least one conducting layer capable of acting as an electrode (elements **16** and **18**), at least one dielectric layer (**14** or **20**), and contact means for allowing electrical contact with at least one conducing layer (for example **18b** and **16b** in Drawing 3(A); also see paragraph [0019] of the *Detailed Description*).

Addressing Claim 2, an aperture defining a non-uniform internal wall in the laminate structure is shown in Drawings 2 and 4-6.

Addressing Claim 4, a plurality of apertures is implied or shown in Drawings 4-6.

Addressing Claim 6, an aperture in the form of a well as claimed may be seen in Drawings 2, 3C, 5, and 6.

Addressing Claim 8, that dielectric layer **20** may be polyisoprene rubber, which inherently absorbs oxygen, is stated in paragraph [0023] of the *Detailed Description*.

Addressing Claim 10, a silicon or polymeric base **(14)** is taught in paragraph [0037] in the *Detailed Description*.

Addressing Claim 11, substantially collinear wells as claimed may be seen in Drawings 4-6.

Addressing Claim 16, a gold conducting layer is disclosed in paragraph [0022] in the *Detailed Description*.

Addressing Claim 23, dielectric layer **14** comprises biological substance **22** (paragraph [0028] in the *Detailed Description*).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1-3, 6, 7, 20, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over JPO computer translation of Toyama et al. (JP 0921778 A) in view of JPO computer translation of Fukuda (JP 06324014 A).

Addressing Claim 1, Toyama et al. teach an electrode system comprising a laminated structure (the abstract and Drawings 1-3), having at least one conducting layer capable of acting as an electrode (elements **14** and **13**), at least one dielectric layer (**16**, **15**, **17**, and **12**), and contact means for allowing electrical contact with at least one conducing layer (**19** and **20**).

Toyama et al. do not mention that the electrode system is a microelectrode system, although they do disclose making the electrodes by vacuum deposition, sputtering, screen-printing, electrolysis plating, or electroless deposition (paragraph [0010] of the Detailed Description), which are all techniques usually used for making microelectrodes.

Fukuda teaches a microelectrode system comprising a laminated structure (the abstract; Drawings 2 and 4-6; paragraph [0022] of the *Detailed Description*; and paragraph [0029] of the *Detailed Description*), having at least one conducting layer capable of acting as an electrode

(elements **16** and **18**), at least one dielectric layer (**14** or **20**), and contact means for allowing electrical contact with at least one conducing layer (for example **18b** and **16b** in Drawing 3(A); also see paragraph [0019] of the *Detailed Description*). In particular, Fukuda teaches electrodes made by vacuum deposition having a thickness of 0.3 micrometers (paragraph [0029] of the *Detailed Description*). It would have been obvious to one with ordinary skill in the art at the time the invention was made have the electrodes have at least one dimension less than 1 mm as taught by Fukuda in the invention of Toyama et al. because this will help keep the overall size of the sensor small, which is desired, as seen in the sections entitled *Effect of the Invention* and *Technical Problem* of Toyama et al.

Addressing Claim 2, an aperture defining a uniform internal wall in the laminate structure is shown in Drawings 1-3 of Toyama et al.

Addressing Claim 3, an aperture defining a substantially tubular internal wall in the laminate structure is shown in Drawings 1-3 of Toyama et al.

Addressing Claim 6, an aperture in the form of a well as claimed may be seen in Drawings 1A, 2A, and 3C of Toyoma et al.

Addressing Claim 7, electrodes **13** and **14** are fictionalized by direct contact with layer **12,** in which glucose oxidase is fixed (paragraph [0006] in the *Detailed Description* of Toyama et al.).

Addressing Claim 10, a polymeric base is implied by paragraph [0014] in the *Detailed Description* of Toyama et al., which teaches that base **17** is made of a flexible resin.

Addressing Claim 20, alternating conducting and dielectric layers are disclosed in Drawings 1-3 of Toyama et al.

Addressing Claim 23, dielectric layer **12** contains an enzyme (paragraph [0006] in the *Detailed Description* and the abstract of Toyama et al.)

12. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over JPO computer translation of Fukuda (JP 06324014 A).

Fukuda teaches a microelectrode system comprising a laminated structure (the abstract; Drawings 2 and 4-6; paragraph [0022] of the *Detailed Description*; and paragraph [0029] of the *Detailed Description*), having at least one conducting layer capable of acting as an electrode (elements **16** and **18**), at least one dielectric layer (**14** or **20**), and contact means for allowing electrical contact with at least one conducing layer (for example **18b** and **16b** in Drawing 3(A); also see paragraph [0019] of the *Detailed Description*). Fukuda further teaches at least one pair of substantially collinear wells having a common bottom in Drawings 4-6. Barring evidence to the contrary, such as unexpected results, having more than one pair of wells is just multiplication of parts, which is obvious. With more wells a greater number of different tests can be performed. Note Claim 2 of Fukuda, which claims more than two test sections.

Allowable Subject Matter

13. Claims 13, 14, 19, and 22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

14. The following is a statement of reasons for the indication of allowable subject matter:

a) Claim 13: in Fukuda the well bottom comprises glass and a biological substance (paragraphs [0027]-[0029] of the *Detailed Description*). Fukuda appears to actually teach away from a material such as ion exchange material because he states that entrapping "elasticity" (polymer membrane ?) is unnecessary to immobilize the biological substance (paragraph [0028] of the *Detailed Description*);

b) Claim 14: none of the cited prior art discloses an organic conducting layer;

c) Claim 19: none of the cited prior art teaches a piezoelectric vibrator or an ultrasonic probe;

d) Claim 22: means to apply physical or chemical gradients to potentials to the specialized layer has not been found in the cited prior art;

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (703) 305-5686. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JILL WARDEN can be reached on (703) 308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Alex Noguerola
December 30, 2002